

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: GALLOWAY, Edward L.; PETERSEN, Eric; GOLIAS, Tipton

SERIAL NO.: 10/792,025

ART UNIT: 3731

FILED: March 3, 2004

EXAMINER: Sonnett, K.

TITLE: LOAD-CONTROLLED DEVICE FOR A PATTERNED SKIN INCISION

AMENDMENT "A"

Director of the U.S. Patent
and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Office Action of May 10, 2006, a response being due by August 10, 2006, please enter the present amendments and consider the following remarks:

REMARKS

Upon entry of the present amendments, previous Claims 1 - 20 have been canceled and new Claims 21 - 37 substituted therefor. Reconsideration of the rejections, in light of the forgoing amendments and present remarks, is respectfully requested. The present amendments have been entered for the purpose of more clearly distinguishing the present invention from the prior art..

In the Office Action, it was indicated that Claims 16 - 18 were rejected under 35 § U.S.C. 102(b) as anticipated by the Thorne patent. Claims 1, 2, 4 - 13 and 19 were rejected under 35 § U.S.C. 103(a) as being obvious over the Thorne patent in view of the Cusack patent. Claims 3 and 20 were rejected under 35 § U.S.C. 103(a) as being unpatentable over the Thorne patent and

the Cusack patent in view of the Rutynowski patent and the Cusack '581 patent. Claim 10 was rejected under 35 § U.S.C. 112, second paragraph, as being indefinite. Claim 8 was objected to because of a typographical error. The Examiner has indicated that Claims 14 and 15 are "objected to" as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims.

As an overview to the present reply, Applicant has extensively amended the original claim language so as to present independent Claims 21, 28, 29, 33 and 35. Each of these independent claims define certain features of the present invention which serve to distinguish the present invention from the prior art.

It is important to note that the present invention achieves many advantages over the existing prior art and the prior art patents identified by the Examiner. As was stated in paragraph [0062] of the original specification:

The controlled action of slicing, both entering and exiting, will minimize the trauma to the skin, will reduce the introduction of undesirable elements of the skin tissue into the incision and blood sample, and will promote the rapid healing of the incision location. The present invention creates a patterned incision by the outward movement of the blade 38, horizontal movement and inward movement of the blade. The patterned incision secures a more standard sample for analysis, unlike the prior art devices which rely upon a puncture or stabbing motion of the blade. Random tearing of the skin at the incision area and inconsistent depth of blade penetration are no longer factors which effect the sample analysis.

The consistent depth of blade penetration is assured by the fact that regardless of the amount of pressure applied to the cover of the present invention, the same amount of force is exerted against the skin. A strong application of force onto the cover (which actuates the blade), will not result

in more force applied by the contact surface of the casing upon the skin. As such, the blade will create the consistent cutting action. This procedure was recited in the original specification, in paragraph [0063] as follows:

The operation of the present invention allows for a designed controlled force to be achieved. The cover 16 will travel vertically over the casing 12. The actuator 46 is restrained at one end by the support member 19 of the casing 12 and contacts the inner surface of cover 16. The opposite end of the actuator 46 is in contact with the release seat 13 of the casing 12. The cover 16 will continue to travel downwardly and the vertical application force is retained in the resilient curved member of the actuator 46 and converted to horizontal displacement of the knuckle 56. At a designed vertical pre-determined force, which is achieved as a function of distance traveled and resilient curved member flexing, the actuator 46 makes contact with the blade 38. The vertical pre-actuation force is released in a horizontal motion, as shown in FIGURES 3-5. This release is controlled by the strength of the leaf spring-like property of the resilient curved member 45.

As such, the present invention achieves the objective of "a controlled vertical force", the objective of "removing variations of force" and "no pre-loaded forces". Applicant respectively contends that these features of the present invention are neither shown nor suggested by the prior art Thorne patent, individually, or in combination with the Cusack '041 patent.

Relative to the new independent claims herein, Applicant has revised original independent Claim 1 in the form of new independent Claim 21. New independent Claim 21 indicates that the carriage means moves the "blade between the pre-actuated position to the post-actuated position with a constant determined force of contact of the bottom surface of the casing of the skin regardless of the force applied to the cover". Additionally, independent Claim 21 specifies that the cover is positioned "over" the casing.

Independent Claim 28 emphasizes the first pivot point and the second pivot point of the

blade. The casing is identified as having a retainer peg. The first pivot point of the blade is connected to the retainer peg by way of an "obround" formed on the blade. The second pivot point is attached to the carriage means.

New independent Claim 29 describes the actuator of the present invention. In particular, the actuator is described in that the "knuckle is spaced from the blade when in the pre-actuated position" and that the knuckle "contacts the blade during movement between the pre-actuated position and the post-actuated position".

New independent Claim 33 incorporates the limitations of previous dependent Claim 14 and the limitations of previous independent Claim 1. Since previous dependent Claim 14 was "objected to", independent Claim 33 should now be allowable.

New independent Claim 35 incorporates the limitations of previous independent Claim 16 and dependent Claim 18. Additionally, it is indicated that the knuckle is spaced from the blade when in the pre-actuated position at that the knuckle contacts the blade during the movement of the blade between the pre-actuated position and the post-actuated position.

In each of these independent claims, Applicant respectively contends that the limitations included therein are neither shown nor suggested by the prior art Thorne patent nor the prior art combination of the Thorne and the Cusack '441 patent.

The Thorne patent does describe a skin incision device. The skin incision device is operated by depressing a button that is located at the top of the device. The button is depressed so as to actuate a pre-loaded spring. In particular, when the button 240 is depressed, an arm extending therefrom will move through the casing so as to dislodge the actuator arm from a preset and pre-loaded position. Once the actuated is dislodged, the actuator will release the load such that the

spring moves the blade between the pre-actuated and the post-actuated position.

In the Thorne patent, it is important to note that the "cover" is not shown as extending over the casing. The Thorne patent utilizes a "button" located within the interior of the casing so as to cover a portion of the actuator spring and to impart forces thereon by way of movement of the arm for the dislodgement of the actuator arm and for the movement of the spring. During actual use, in order to depress the button, it is very likely that the sides of the casing would have to be grasped with the thumb and middle finger while the forefinger moves the button downwardly. When the sides of the casing are grasped, variable (not constant) force will be applied between the bottom surface of the casing and the skin to which the device is applied. The Thorne patent also lacks the "obround" that is formed on the blade. In the illustration of Figures 20 - 24 of the Thorne patent, it can be seen that the blade has a circular hole through which a portion of the actuator spring extends. If the hole 344 were, in fact, an obround (or "obvious" as suggested by the Examiner), Applicant respectfully contends that it would not carry out the proper motion and would not carry out the proper incision. Quite clearly, the path of the blade in the Thorne patent is defined by the use of the track 276. The use of an obround on the blade 310 would simply create wobbling and imprecise motion during the movement of the actuator arm through the carriage track.

It is suggested by the Examiner that the Thorne patent utilizes a knuckle 342. It appears that the "knuckle 342" is in fact the point of attachment between the end of the spring opposite to the connection with the blade 310. The knuckle 342 is fixed in place. As such, it would never contact the blade 310 during the movement of the blade through the track 276. The knuckle 342, unlike the present invention, contributes nothing to the movement of the blade itself.

In the Thorne patent, the blade 310 does not have two (2) pivot points. It appears that the

blade 310 only has a single pivot point, that is, the connection with the actuator arm. If the blade 310 actually did have two (2) pivot points, then it could not move in its desired pattern through the track 276. There does not appear to be any “retainer peg” affixed to the casing.

It is quite clear that the Thorn patent operates in an entirely different manner than that of the present invention. In the present invention, the cover is depressed so as to move the actuator arm resiliently downwardly. The curved portion of the actuator arm will contact surfaces within the casing so as to dislodge the knuckle. When dislodged, the knuckle of the present invention contacts the blade 76 so as to cause the cam 64 to move in a desired pattern over the guide member 15 for the purposes of moving the blade 38 along the pivot point 82 associated with the obround. The present invention does not utilize the guide track 276 of the Thorne patent. The present invention does not maintain constant contact between the actuator 45 and the blade 38. The blade 38 is not “pre-loaded” within the casing. It is only the horizontal movement of the knuckle 46, in combination with the actuator 45, which creates the requisite movement of the blade across the guide member 15 by way of contact with the cam surface 64. Because of the horizontal movement which creates the incision caused by the razor 76 of blade 38, it does not matter whether weak forces or strong forces are applied to the cover. In the Thorne patent, the gripping forces on the side of the casing during the pressing of the button 240 cause different forces to be imparted between the bottom surface of the casing of the Thorne patent and the skin of the person being incised. Fundamentally, when viewing the Thorn patent, it is difficult to believe that “one having ordinary skill in the art” could configure the spring-like structure of the Thorne patent into the structure of the present invention.

The prior art Cusack patent describes a completely different lancet assembly than that of the Thorne patent. Fundamentally, it is difficult to see how one could combine the teachings of the

Cusack patent with the Thorne patent in order to achieve the structure of the present invention. The Cusack patent utilizes a slide button that is depressed in a direction generally parallel to the bottom surface 12 of the casing. The button 20 is interconnected to the trigger projection 98 on the pivot arm member 92. A blade is affixed to the pivot arm member. The pivot arm member 92 has a slot at a bottom therein so as to allow the pivot arm member to slide upwardly and downwardly for the creation of the incision. The pivot arm member 92 is preloaded by retracting the spring 122 within the interior of the casing. When the button 20 is pushed in the direction parallel to the bottom surface 12, the distal end 118 of the button will eventually free from the trigger hook projection 98 of the pivot arm member 92. This causes the spring 122 to immediately to push the pivot arm member 92 in an opposite direction. During this movement, a cam follower 112 passes through a cam guide channel 68 so as to create the requisite cut.

Fundamentally, the Cusack patent does not have any "cover" extending over the casing. Since the sides of the casing are usually gripped during the pressing of the button 20, different forces can be applied downwardly such that varying forces can occur between the bottom surface 12 and the skin of the person being incised. The actuator appears to be the spring 122. There is no "obround" formed in the blade 104. Unlike the present invention, the Cusack patent does not utilize a first pivot point on the blade connected to the retainer peg and a second pivot point attached to the carriage means. Quite clearly, the peg 112 is a pin that follows the path of the cam guide.

Relative to the application of prior art to each of the claims of the present application, Applicant respectively contends that the prior art, individually or in combination, fails to show the structure of the present invention as defined by independent claims. In particular, independent Claim 21 specifies that the carriage means moves the blade to the pre-actuated position to the post-actuated

position "with a constant determined force of contact of the bottom surface of the casing with the skin regardless of the force applied to the cover". Independent Claim 21 also specifies that the cover is positioned "over" the casing. Neither the Cusack patent or the Thorne patent utilizes a "cover" applied over the casing. The Thorne patent utilizes a button located within the casing. The Cusack patent utilizes a slide button located at the top of the casing. In each case, both the Thorne patent and the Cusack patent would require a grasping of the casing with the thumb and middle finger prior to the application of the actuating force by the pressing of the button with the forefinger of the user. When the sides of the casing are grasped, varying forces can be applied between the bottom surface of the casing and the surface of the skin. The present invention overcomes this problem by placing a large cover over the casing so that the cover can be grasped, in any manner, during the application of force. Since the actuation of the blade is not dependent upon the amount force applied to the cover, a constant force and regular cut is achieved by the blade during the incising operation. On this basis, Applicant contends that independent Claim 21, as amended, is patentably distinguishable from the Thorne patent, individual, or the Thorne patent in combination with the Cusack patent.

Dependent Claims 22 - 27 reflect the limitations, respectively, of original dependent Claims 2 - 7.

Independent Claim 28 incorporates the limitations of previous dependent Claims 8 and 9 into the language of independent Claim 1. Independent Claim 28 specifies that the casing has a retainer peg therein. The blade has a first pivot point, which is an obround, formed in the blade and positioned over this retainer peg. The blade is also identified as having "a second pivot point attached to the carriage means" and that the first pivot point is in rotatable and in cam relation to the casing during the movement of the blade from the pre-actuated position to the post-actuated position.

Quite clearly, the Thorne patent fails to show these two pivot points associated with the blade 310. The Thorn patent does not show an “obround” formed in the blade, but rather an entirely circular hole. It would not be obvious to use such an “obround” since the obround would affect the ability of the blade 310 to travel in its desired manner. The blade could wobble or move upwardly and downwardly during the path directed by the track 276. Quite clearly, the Thorne patent does not utilize the second pivot point of the blade which is attached to the carriage means. It does not appear that the first pivot point of the blade and the Thorne patent is, in any way, “connected to said casing”. The pivot point appears to be directly connected to the actuator spring 320. On this basis, Applicant contends that independent Claim 28 is not anticipated by the Thorne patent. Once again, the combination of the Thorne patent and the Cusack patent would fail to show the structure of the present invention as defined by independent Claim 28.

Fundamentally, one would have great difficulty in determining how the “two pivot points” illustrated in the Cusack patent could, in any way, be integrated into the structure of the Thorne device. The pivot point 112 in the Cusack patent is not “connected to the casing”, but rather connected to the pivot arm 92 so that the pivot arm 92 could slide in a desired manner through the cam guide 68. If the pivot point 112 were connected to the casing, then proper movement of the pivot arm 92 could not be achieved. The Cusack patent also lacks the “obround” as formed on the blade. There is a U-shaped portion 110 in the Cusack patent, but this is not an obround, nor is it formed on the blade. On this basis, Applicant respectively contends that the limitations found in new independent Claim 28 are neither shown nor suggested by the prior art combination of the Thorne and Cusack patents.

Independent Claim 29 serves to describe the actuator of the present invention. In particular,

new independent Claim 29 incorporates the limitations in independent Claim 1 and the limitations of dependent Claim 10. Independent Claim 29 further recites that the “knuckle is spaced from the blade when in the pre-actuated position” and that the knuckle “contacts the blade during movement between the pre-actuated position and the post-actuated position”. Relative to the Thorne patent, if the knuckle is the post 344 in the Thorne patent, then it is not spaced from the blade when in the pre-actuated position. If the knuckle in the Thorne patent is the support 342, then such a “knuckle” does not “contact the blade during movement between the pre-actuated position and the post-actuated position”. The Cusack patent does not show such a knuckle, in any way. On this basis, Applicant respectively contends that independent Claim 29 is patentably distinguishable from the Thorne patent, individually, and from the Thorne and Cusack patents in combination.

Dependent Claims 30 - 32 reflect the limitations, respectively, of original Claims 11 - 13.

Independent Claim 33 incorporates the limitations of objected-to Claim 14 and base Claim 1. As such, independent Claim 33 should be in a proper condition for allowance. Dependent Claim 34, which depends on allowable independent Claim 33, incorporates limitations of previous dependent Claim 15. Dependent Claim 34 should similarly be allowable.

Independent Claim 35 includes the limitations of independent Claim 16 and the limitations of dependent Claim 18. In particular, it is recited relative to dependent Claim 18 (now incorporated in independent Claim 35) that the knuckle is spaced from the blade in the pre-actuated position and that the knuckle contacts the blade during movement between the pre-actuated position and the post-actuated position. As stated with respect to the arguments pertaining to independent Claim 29, the prior art Thorne patent cannot carry out such an action nor display such a structure. Similarly, the Cusack patent lacks such a structure. On this basis, Applicant contends that independent Claim 35

is patentably distinguishable from the prior art Thorne patent, individually, and in combination with the Cusack patent. Dependent Claim 36 reflects the limitations of previous dependent Claim 17. Dependent Claim 37 reflects the limitations of previous dependent Claim 19.

Relative to the formality objections by the Examiner, those objections relative to previous dependent Claims 8 and 10 have been corrected in the new claims corresponding thereto.


Based upon the foregoing analysis, Applicant contends that independent Claims 21, 28, 29, 33 and 35 are now in proper condition for allowance. Additionally, those claims which are dependent upon these independent claims should also be in condition for allowance. Reconsideration of the rejections and allowance of the claims at an early date is earnestly

solicited. Since one new independent claim has been added above those originally paid for an additional fee of \$200 is attached hereto.

Respectfully submitted,

Date

8.7.06



John S. Egbert
Reg. No. 30,627
Andrew W. Chu
Reg. No. 46,625
Attorney for Applicant
Egbert Law Offices
412 Main Street, 7th Floor
Houston, Texas 77002
(713)224-8080
(713)223-4873 fax

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: GALLOWAY, Edward L.; PETERSEN, Eric; GOLIAS, Tipton

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CERTIFICATE OF MAILING UNDER 37 CFR 1.8(a)

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

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AMENDMENT "A"

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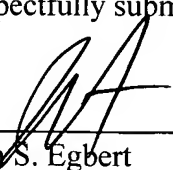
AUG 07 2006

on

Respectfully submitted,

AUG 07 2006

Date



John S. Egbert
Reg. No. 30,627
Attorney for Applicant
Egbert Law Offices
412 Main Street, 7th Floor
Houston, Texas 77002
(713)224-8080